

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	MDL NO. 1203

THIS DOCUMENT RELATES TO:)	
SHEILA BROWN, et al.)	
v.)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8598

Bartle, C.J.

February 8 , 2011

Karen Osborne ("Ms. Osborne" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Edwin Osborne, Ms. Osborne's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In September, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, W. Marcus Brann, M.D., F.A.C.C. Dr. Brann is no stranger to this litigation. According to the Trust, he has attested to at least 764 Green Forms on behalf of claimants seeking Matrix Benefits, including more than 50 on the same day he signed Ms. Osborne's Green Form. Based on an echocardiogram dated May 16, 2002, Dr. Brann attested in Part II of Ms. Osborne's Green Form that she suffered from moderate mitral regurgitation, an abnormal left

3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

atrial dimension, and an ejection fraction in the range of 50% to 60%.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$476,887.⁵

In the report of claimant's echocardiogram, the reviewing cardiologist, James D. Watson, M.D., F.A.C.C., stated that claimant had a "moderate degree" of mitral regurgitation, which he measured to be 24%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In February, 2004, the Trust forwarded the claim for review by R. Parker Ward, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Ward concluded that there was no reasonable medical basis for Dr. Brann's finding that claimant had moderate mitral regurgitation because "[w]hen appropriate [mitral regurgitant] jet is traced, jet is < 20% [of the left atrial] area."

4. Dr. Brann also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

Based on Dr. Ward's finding of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Osborne's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted the declaration of Robert N. Notske, M.D., F.A.C.C., F.A.C.P. In his declaration, Dr. Notske stated that:

There is a very nice apical 4-chamber view in which the [mitral regurgitant] jet is easily traceable to measure greater than 20% of the [left atrial] area. My interpretation supports that of the Attesting Cardiologist, W. Marcus Brann, M.D., FACC, whom I have not met and whom I do not know.

In response, the Trust forwarded the claim for a second review by Dr. Ward, who confirmed his conclusion that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because "[c]laimant's level of mitral regurgitation is only mild in real time, with an RJA/LAA ratio of 10-15%." Specifically, Dr. Ward observed:

The planimetry of Claimant's mitral regurgitant jet area ("RJA") upon which Claimant's Attesting Physician and expert rely appears on the first of two stop frame RJA measurements on Claimant's echocardiogram. On this stop frame, the sonographer measured Claimant's RJA at

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Osborne's claim.

5.59 cm². This measurement, however, constitutes a gross exaggeration of the actual regurgitant jet, with substantial overtracing of the RJA to include non-regurgitant flow. Moreover, the mitral regurgitant jet appearing on this stop frame cannot be seen in real time on Claimant's echocardiogram. On the RJA measurement appearing on the second stop frame of Claimant's echocardiogram, the sonographer measured Claimant's RJA at 4.14 cm². This measurement is also slightly exaggerated, with overtracing of the RJA to include non-regurgitant flow.

* * *

The sonographer correctly planimetered a representative left atrial area ("LAA") appearing on Claimant's echocardiogram at 23.55 cm². Even using the second of the overtraced RJA measurements appearing on Claimant's echocardiogram (of 4.14 cm²), this LAA yields an RJA/LAA ratio below the 20% threshold for moderate mitral regurgitation under the Settlement Agreement.

Based on my evaluation and review, I conclude that Claimant clearly has mild mitral regurgitation with an RJA/LAA ratio of no more than 15%.

The Trust then issued a final post-audit determination, again denying Ms. Osborne's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO NO. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Osborne's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5241 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on September 29, 2005, and claimant submitted a sur-reply on October 25, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁷ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue,

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Osborne argues that her attesting physician's Green Form responses are supported by a reasonable medical basis because Dr. Watson, Dr. Brann, and Dr. Notske all agreed that claimant's RJA/LAA ratio was greater than 20%, and Dr. Brann and Dr. Notske followed the Weyman and Feigenbaum texts. In addition, claimant argues that "the auditor failed to give precise measurements or tell the Claimant precisely why no reasonable medical basis existed for Dr. Brann's conclusion that she had moderate mitral regurgitation."

In response, the Trust argues that claimant failed to meet her burden of establishing a reasonable medical basis for her claim because the expert opinion of Dr. Notske "merely parrots the findings of Dr. Brann" and does nothing to refute Dr. Ward's conclusions. Further, the Trust notes that, as stated in Dr. Ward's declaration, Dr. Brann and Dr. Notske "relied upon [the] same improper planimetry." In addition, the Trust asserts that the auditing cardiologist conducted the audit in accordance with the Settlement Agreement and Audit Rules.⁸

8. The Trust also argues that under Rule 26(a)(2) of the Federal (continued...)

In her sur-reply, claimant submitted a supplemental declaration of Dr. Notske. Dr. Notske stated that he reviewed the Feigenbaum and Weyman texts and disagreed that the tracing on claimant's echocardiogram was "a gross exaggeration." According to Dr. Notske, the Feigenbaum text states that "'one should take the entire mitral regurgitant jet, including the surrounding lower flow spray' into account for purposes of determining the regurgitant jet area."

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and observed that the echocardiogram of May 16, 2002 demonstrated only mild mitral regurgitation. Specifically, Dr. Vigilante stated that:

There was minimal mitral regurgitation suggested in the parasternal long-axis view. The mitral regurgitation was most impressively seen in the apical four chamber view. This was a mild degree of mitral regurgitation with the jet traveling slightly laterally within the left atrium. This jet did not reach the mid portion of the left atrium. I digitized several representative cardiac cycles and made measurements of the RJA and LAA off-line. The RJA/LAA ratio was less than 14% in those cycles where the mitral regurgitation appeared the worst. Most of the cardiac cycles demonstrated RJA/LAA ratios of less than 10%. In addition, the RJA/LAA ratios were less than 10% in the apical two chamber views. Several measurements were made by the sonographer.

8. (...continued)

Rules of Civil Procedure, physicians who proffer opinions regarding claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. We disagree. We previously stated that Rule 26(a)(2) disclosures are not required under the Audit Rules. See PTO No. 6996 at 7 n.10 (Feb. 26, 2007).

The measurement of the LAA was appropriate. However, two measurements of the RJA made by the sonographer were definitely inaccurate. The RJA measurement of 5.59 cm² was made in a non-representative still frame that could not be found in real-time. In addition, the distal part of this supposed RJA was lower velocity and non-mitral regurgitation flow. The accurate RJA was much less than the two values measured by the sonographer. The inaccurate measurement of 5.59 cm² made by the sonographer is the exact same measurement used by Dr. Watson on his formal echocardiogram report. The accurate RJA/LAA ratio was less than 14% in all views. The RJA/LAA ratio never approached 20%.

* * *

In response to Question 1, there is not a reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, the echocardiogram of May 16, 2002 demonstrated only mild mitral regurgitation with comments as noted above.

In response to the Technical Advisor Report, claimant argues that the Technical Advisor did not apply the Feigenbaum standards as required by the Settlement Agreement because he relied on "the most representative regurgitant jet" rather than "the 'maximum regurgitant jet'" and he failed to include "'lower flow spray.'" In addition, claimant argues that the still frame measuring 5.59 cm² establishes a reasonable medical basis for Dr. Brann's diagnosis of moderate mitral regurgitation.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. Contrary to claimant's contention, the opinions of Dr. Watson, Dr. Brann, and Dr. Notske do not provide a reasonable medical basis for the attesting physician's Green Form representation that Ms. Osborne had

moderate mitral regurgitation. We previously explained in PTO No. 2640 that conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, the auditing cardiologist and the Technical Advisor determined, and Ms. Osborne's cardiologists do not adequately contest, that the measurements submitted in support of her claim are inappropriate.⁹ Specifically, Dr. Vigilante observed that "two measurements of the RJA made by the sonographer were definitely inaccurate. The RJA measurement of 5.59 cm² was made in a non-representative still frame that could not be found in real-time." Dr. Vigilante also found that "the distal part of this supposed RJA was lower velocity and non-mitral regurgitation flow." Such unacceptable practices by Ms. Osborne's cardiologists cannot

9. For this reason as well, we disagree with Ms. Osborne that Dr. Ward did not "tell the Claimant precisely why no reasonable medical basis existed for Dr. Brann's conclusion that she had moderate mitral regurgitation."

provide a reasonable medical basis for the resulting diagnosis and Green Form answer.

We also reject claimant's assertion that she may recover Matrix Benefits based on a single maximum measurement of her level of mitral regurgitation. In support, claimant argued that she was diagnosed with moderate mitral regurgitation based on the "sonographer's measurement of the maximum mitral regurgitant jet." We previously have held that for a reasonable medical basis to exist, a claimant must establish that the finding of the requisite level of mitral regurgitation is representative of the level of regurgitation throughout the echocardiogram.¹⁰ See PTO No. 6997 at 10-11 (Feb. 26, 2007). To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement.

Moreover, we previously have stated that "[o]nly after reviewing multiple loops and still frames can a cardiologist reach a medically reasonable assessment as to whether the twenty percent threshold for moderate mitral regurgitation has been achieved." PTO No. 6897 at 7 (Jan. 26, 2007) (quoting

10. Under the Settlement Agreement, moderate or greater mitral regurgitation is defined as a "regurgitant jet area in any apical view equal to or greater than twenty percent (20%) of the left atrial area (RJA/LAA)." Settlement Agreement § I.22. Nothing in the Settlement Agreement suggests that it is permissible for a claimant to rely on isolated instances of what appears to be the requisite level of regurgitation to meet this definition.

PTO No. 2640 at 9). As claimant has not established that the "maximum mitral regurgitant jet" offered in support of her claim is representative of her level of mitral regurgitation, claimant has failed to establish a reasonable medical basis for her claim. This is especially true where, as here, the Technical Advisor concluded that claimant's echocardiogram demonstrated only mild mitral regurgitation because the RJA/LAA ratio was less than 14% in those representative cardiac cycles where the mitral regurgitation appeared the worst. Rather than rebutting this specific determination made by the Technical Advisor, claimant relies solely on an erroneous interpretation of the Settlement Agreement.¹¹ On this basis as well, claimant has failed to meet her burden.

We also disagree with claimant's argument that the auditing cardiologist inappropriately did not provide "precise measurements." Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiologist." PTO No. 2640 at 15. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements

11. We also reject claimant's argument that the Technical Advisor applied an improper standard in determining that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation.

of mitral regurgitation be made to determine if a claimant qualifies for Matrix benefits. There is no basis for such a revision, and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.¹²

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Osborne's claim for Matrix Benefits and the related derivative claim submitted by her spouse.

12. In any event, the Technical Advisor, although not required to do so, made specific measurements of claimant's level of mitral regurgitation, which further establish that claimant is not entitled to Matrix Benefits.